EVANSTON NORTHWESTERN HEALTHCARE

Evanston Hospital

MEMO

November 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Re: Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents..., Proposed Rule [Docket No. 98N-0581]

To whom it may concern:

The proposed rule listed above would mandate transfusion-transmitted disease testing of all units of blood intended for autologous transfusion, canceling the current exemption from testing for autologous blood which will be transfused within the same facility in which it is collected. We believe that this change is unnecessary and unproductive. The discussion that follows is organized by the rationales advanced for canceling this exemption.

I. Testing all autologous blood will protect recipients other than the donor from inadvertent transfusion of test-positive units.
   A. This would only be the case if autologous units with positive tests were discarded. However, the proposed rule allows test-positive autologous units to be retained as long as they are labelled as biohazardous. In fact, it is likely that this is the course which most institutions would follow for two reasons: first, it is our experience that autologous donors with diseases such as HCV or HIV infection will request to have an autologous blood option; second, in view of the recent Bragdon v. Abbott decision it is likely that hospitals will not resist such requests. Thus such institutions will simply segregate test-positive units, and label them with "biohazard stickers". The same outcome could be achieved simply by mandating biohazard labeling of all untested units.
   B. Even though tested, autologous units will not have the same safety profile as allogeneic donor units unless we also require autologous donors to meet allogeneic screening criteria for recipient protection. Such a requirement would make many autologous donors ineligible, and even performing this screening would have a significant negative impact on autologous transfusion practices.
   C. The real issue is the efficacy of an institution's process for ensuring transfusion of any unit of blood to the intended recipient. There are many potential regulations that would more directly address this issue such as:
      1. Requiring more prominent labeling of autologous units. Currently the autologous units our blood center sends us are prominently labeled "Volunteer Donor", with a 1"x1½" green rectangle elsewhere on the label indicating "For autologous use only" in much smaller type (see attachment). Instead, the autologous units that we draw have fluorescent green base labels that can be recognized across the operating room, and have been.
      2. Requiring that more than one individual identify the recipient at the time of transfusion.

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II. Testing autologous units would prevent errors because all units would be handled in the same fashion. In particular, testing all autologous blood will prevent release of a unit inadvertently crossed over into the allogeneic supply.

A. For hospitals that do not test autologous units and do not use the same donor questionnaire for autologous and allogeneic donors, there is nothing that is similar about the two processes. In fact, it could be argued that "handling all units the same" increases the risk of inadvertent crossover. Thus, in our current process there is no reasonable scenario for the postulated confusion.

B. This could more economically be addressed by requiring a prominent autologous label to be placed while the needle is in the donor's arm, as is our hospital's current practice.

C. The AABB already proscribes crossover of autologous units (standard L1.120) except in exceptional circumstances. This could be made a FDA regulation. It would then behoove blood centers to have a validated process to make sure that inadvertent crossover does not occur.

III. Testing all autologous units will protect hospital personnel against inadvertent exposure to blood when units break.

A. This rationale is similar to discredited rationales for HIV testing of all patients admitted to a hospital or going to the operating room. Universal precautions were instituted to address this issue.

B. Again, this only works if all test-positive units are discarded.

C. Exposures to infectious units from perioperative collections (acute normovolemic hemodilution and intraoperative salvage) will not be prevented.

IV. Testing all autologous units would provide hospital personnel involved in an inadvertent exposure to blood from such a unit with information that would be useful in deciding whether to initiate anti-HIV therapy.

A. If such an exposure occurred in the collecting hospital, the source patient would be immediately available for testing, as is any other patient who is the source of a blood exposure.

B. This rationale might be appropriate for blood center personnel or others handling the unit before it reaches the hospital. Currently such a case is not subject to the testing exemption.

V. Testing all autologous blood will prevent errors in which plasma from such units is salvaged for further manufacture.

A. Again, this only works if all test-positive units are discarded.

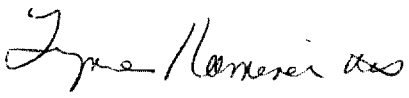
B. It is unlikely that any institution collecting autologous units that are subject to the current testing exemption (i.e. the units don't leave the institution) is salvaging plasma for further manufacture. Such units are typically kept as whole blood for use in surgery. One could simply require an exempt institution to either test all units or to refrain from preparing salvaged plasma.

In our opinion, all of the rationales for testing autologous units are hypothetical and fall apart when the actual processes for collection of test-exempt units are examined. The proposed rule states that a "significant" improvement in safety would result, but testing autologous units which stay within an institution will not directly address the problem of transfusion of blood intended for patient 'Smith' into patient 'Jones'. And there is no evidence for the proposed improvement in safety; instead, it is projected based on process problems that are not directly addressed. We believe that there are virtually no situations in which this change in regulation will improve patient care or safety, and that there are several other regulatory changes (better labeling, no-crossover) that would better address the real issues.

Although autologous donation has been characterized as cost-INeffective, all such calculations have included the cost of testing. As practiced at our hospital and other similar institutions, autologous donation/transfusion is actually quite simple and inexpensive. Unfortunately, the proposed regulation would eliminate this advantage, costing our institution $53,000 per year, a 3% increase in our budget. Physicians are well aware of the costs of treatment, particularly those physicians who, like ourselves, are involved in the construction of protocols for clinical management in defined patient circumstances (e.g. radical prostatectomy, major joint surgery, etc.). Any increased cost of autologous blood is bound to have a chilling effect on its use. What evidence do we have that the INCREASED aggregate risk from increased use of allogeneic transfusion, with its known hazards including transfusion-mediated immunomodulation, would not outweigh any minor improvement in safety due to testing?

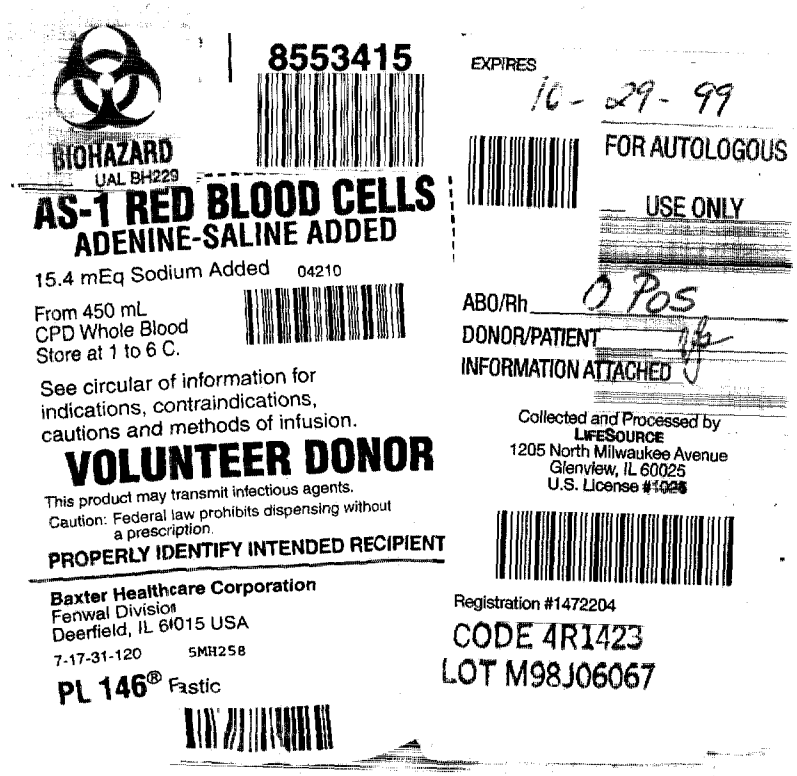
Sincerely,

James T. Perkins, M.D.
Director, Evanston Northwestern Healthcare, Blood Banks
Assistant Professor, Northwestern University Medical School



Lynne Kaminer, M.D.
Hematology Division Head, Evanston Northwestern Healthcare
Chairperson, Transfusion Committee, Evanston Northwestern Healthcare
Assistant Professor, Northwestern University Medical School

WHICH IS BETTER?



BIOHAZARD
UAL BH229

8553415

EXPIRES 10-29-99

FOR AUTOLOGOUS USE ONLY

AS-1 RED BLOOD CELLS
ADENINE-SALINE ADDED

15.4 mEq Sodium Added 04210

From 450 mL
CPD Whole Blood
Store at 1 to 6 C.

ABO/Rh O Pos
DONOR/PATIENT
INFORMATION ATTACHED ✓

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR

This product may transmit infectious agents.
Caution: Federal law prohibits dispensing without a prescription.

PROPERLY IDENTIFY INTENDED RECIPIENT

Collected and Processed by
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1205 North Milwaukee Avenue
Glenview, IL 60025
U.S. License #1026

Baxter Healthcare Corporation
Fenwal Division
Deerfield, IL 60015 USA

Registration #1472204

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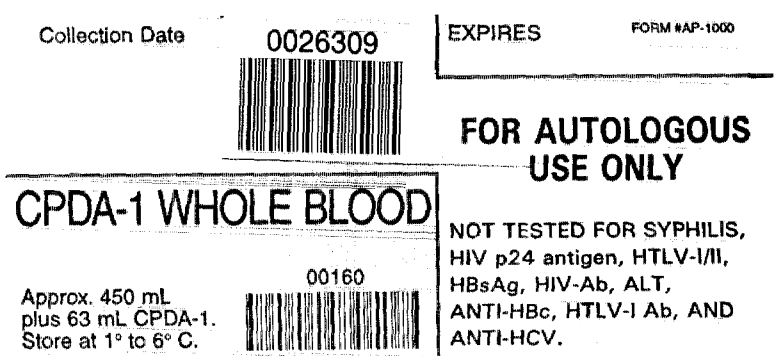

Collection Date 0026309

EXPIRES FORM #AP-1000

FOR AUTOLOGOUS USE ONLY

CPDA-1 WHOLE BLOOD

00160

Approx. 450 mL
plus 63 mL CPDA-1.
Store at 1° to 6° C.

NOT TESTED FOR SYPHILIS, HIV p24 antigen, HTLV-I/II, HBsAg, HIV-Ab, ALT, ANTI-HBc, HTLV-I Ab, AND ANTI-HCV.

See Circular of Information for indications, contraindications, cautions and methods of infusion.

AUTOLOGOUS DONOR

This product may transmit infectious agents.
Caution: Federal law prohibits dispensing without a prescription.

PROPERLY IDENTIFY INTENDED RECIPIENT

ENH EVANSTON NORTHWESTERN HEALTHCARE

Evanston Hospital
2650 Ridge Ave.
Evanston, Illinois 60201

Registration #1473456

DONOR NAME _____

HOSPITAL _____ SURGERY DATE: _____

Social Security # _____ BLOOD GROUP: _____

SPG13

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1 From

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Dept/Floor/Suite/Room

City EVANSTON State IL ZIP 60201

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*Dangerous Goods cannot be shipped in FedEx packaging.

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* When declaring a value higher than $100 per shipment, you pay an additional charge. See **SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY** section for further information.

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